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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/623,200	07/18/2003	Thomas P. Osypka	(49363) 58952	2841
21874 7590 12/13/2007 EDWARDS ANGELL PALMER & DODGE LLP P.O. BOX 55874 BOSTON, MA 02205			EXAMINER HELLER, TAMMIE K	
			ART UNIT 3766	PAPER NUMBER
			MAIL DATE 12/13/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/623,200	OSYPKA, THOMAS P.	
	Examiner	Art Unit	
	Tammie Heller	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 4-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 4-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The amendment filed on October 15, 2007 has been received and considered. By this amendment, claim 1 has been amended and claims 1 and 4-10 are pending in the application.

Response to Arguments

2. Applicant's arguments filed October 15, 2007 have been fully considered but they are not persuasive. Applicant argues that the threaded engagement portion taught by Westlund is not integrally formed with the engagement stem or located longitudinally distal to the proximal tip portion. As an initial matter, Applicant's attention is directed to Figure 9 of Westlund, where it can be seen that the proximal tip portion of the pin 860 extends proximally beyond the threads of the threaded engagement portion. Therefore, the threaded engagement portion is located longitudinally distal to the proximal tip portion. Furthermore, in response to applicant's argument that that the threaded engagement portion taught by Westlund is not integrally formed with the engagement step, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). Westlund teaches that it was known at the time of the invention to provide a threaded engagement portion on the engagement portion of a connector assembly in order to connect an elongated lead body to a ported connector.

Therefore, the combination of the invention of Clemens with the teachings of Westlund discloses each and every aspect of the currently claimed subject matter, including an engagement step including a proximal tip portion and a threaded engagement portion, integrally formed with the engagement stem, longitudinally distal to the proximal tip portion.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1 and 4-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clemens et al. (2002/0077684) in view of Westlund et al. (2002/0077683).

Regarding claim 1, Clemens shows an elongated lead body having opposed proximal and distal end portions and having a first and second lumen extending therethrough; an electrode assembly (16) operatively associated with the distal end portion of the lead body; a connector assembly (50) operatively associated with the proximal end portion of the lead body, the connector assembly having an engagement stem (54) depending proximally therefrom and the first and second lumens extend through the engagement stem of the connector assembly and including a proximal tip portion and a detachable ported connector fitting (58) having a main body portion (54) and a branch portion (61) which extends from the main branch portion, and the main body portion has an engagement bore at the distal end and a proximal receiving section

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configured to receive the proximal tip portion of the engagement stem and the main body portion (54) of the ported connector fitting having a primary passageway extending therethrough having at least one passageway (104) extending therethrough to align and communicate with a first lumen (114) and the branch portion (61) of the ported connector fitting having a secondary passageway extending therethrough to align and communicate with a second lumen (104) of the lead body through the engagement stem of the connector assembly when the ported connector fitting is engaged with the connector assembly (Figs. 1-2).

Although Clemens shows a connector assembly with an engagement stem (54) and ported connector with an engagement bore, and it isn't clear how they are coupled, Clemens fails to specifically show the engagement stem and engagement bore are threaded. Attention is directed to Westlund who shows a similar connector assembly (860) and ported connector (820) that utilizes threads for coupling the connector assembly and ported connector (Fig. 9). It would have been obvious to one with ordinary skill in the art at the time the invention was made to employ threads on the engagement stem and engagement bore for the coupling of the engagement stem and engagement bore of Clemens wherein so doing would amount to mere substitution of one functional equivalent for another that would work equally well on the Clemens device. MPEP 2144.06, *In re Fout*, 675 F.2d 297, 213 USPQ 532 (CCPA 1982).

Regarding claim 4, Clemens shows at least one passageway formed in the ported connector (58) fitting has a funnel-shaped inlet region (where stylet assembly 62 is introduced), but it unclear as to whether the second passageway in the ported

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connector fitting (61) also has a funnel shaped inlet region. It would have been an obvious matter of design choice to include a second funnel shaped inlet region for the second passageway since such a modification would have involved a mere a mere duplication of parts. It has long been held that a mere duplication of parts has no patentable significance unless a new and unexpected result is produced. *In re Harza*, 274 F.2d 669, 124 USPQ 378 (CCPA 1960).

With respect to claims 5-6, Clemens shows a first lumen (114) formed in the lead body has an outlet port at the distal end of the lead body and at a second lumen (104) formed in the lead body has an outlet port (102) at a location spaced from the distal end of the lead body (Fig. 2).

Regarding claim 7, Clemens shows the electrode assembly is bipolar and includes a distal tip electrode (16) and a proximal ring electrode (20) (Fig. 2).

With respect to claim 8, Clemens shows a helical conductor coil (138, 140) extending through the lead body for connecting the electrode assembly with the connector assembly (para. [0047]).

Regarding claim 9, Clemens discloses a helical fixation screw operatively associated with the distal end of the lead body for actively securing the lead to cardiac tissue (Col. 7, line 46-51).

With respect to claim 10, Clemens shows a plurality of flexible tines (162) provided at the distal end of the lead body.

The statements of intended use have been carefully considered but are not considered to impart any further structural limitations over the prior art. The designation

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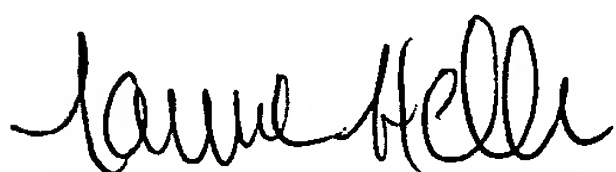
of one lumen as a guidewire lumen and a second lumen as a fluid delivery lumen has been deemed to be statements of intended use.

Conclusion

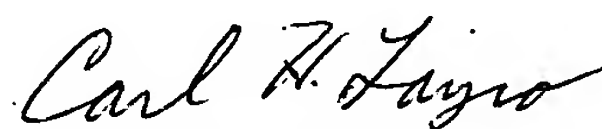
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tammie Heller whose telephone number is 571-272-1986. The examiner can normally be reached on Monday through Friday from 7am until 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl H. Layno can be reached on 571-272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Tammie K. Heller
Patent Examiner
Art Unit 3766



CARL LAYNO
PRIMARY EXAMINER